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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/820,653

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Sudhakar Kasina

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07/14/2005

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EXAMINER

HARTLEY, MICHAEL G

ART UNIT

PAPER NUMBER

1618

DATE MAILED: 07/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/820,653

Applicant(s)

KASINA ET AL.

Examiner

Michael G. Hartley

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 October 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 66-83 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 66-83 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 April 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 10/29/04.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Response to Amendment

The preliminary amendment filed 10/29/2004 has been entered. Consequently, claims 66-83 are pending and have been examined herein.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 66, 73-76 and 81-83 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reutelingsperger (US 5,627,036) in view of Patz (EP 163 294).

Reutelingsperger discloses conjugates comprising an annexin and a chelating compound, see abstract and column 5, lines 62-67. The chelating agents bind various radionuclides, (e.g., Tc-99m) for be useful as a radiopharmaceutical, i.e., a radiodiagnostic, see column 5, lines 50-51.

Reutelingsperger fails to teach the use the same types of chelating agents as instantly claimed, i.e., N_xS_y chelates. However, such chelates are well known in the art as being useful for binding radiometals in radiopharmaceuticals, as shown by Patz.

Patz discloses chelating agents of formula I on page 6 which encompass those instantly claimed. Patz teaches that these chelating agents are especially useful for chelating Tc-99m for use in radiopharmaceuticals, see abstract.

It would have been obvious to one of ordinary skill in the art to modify the conjugates disclosed by Reutelingsperger by using N_xS_y chelates because Reutelingsperger provides a teaching annexins may be bound to chelating agents generally to provide a radiodiagnostic label, and, as shown by Patz, the N_xS_y chelates are well known in the art of radiodiagnostics to be because especially useful for binding Tc-99m (which is one of the most preferred radiometal for radiodiagnostics, as shown by both Reutelingsperger

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and Patz). Given the general teaching of binding chelating agents to annexins to provide the annexin with a radiodiagnostic use as disclosed by Reutelingsperger, one of ordinary skill in the art would have been motivated to employ improved chelating agents or those that are recognized at least as equivalent in the art, such as, N_xS_y chelates as disclosed by Patz because the use of equivalent or improved chelating agents is common in the art of radiodiagnostics to provide optimal radiometal binding for a desired radiopharmaceutical, as shown by both Reutelingsperger and Patz.

Claim 72 is rejected under 35 U.S.C. 103(a) as being unpatentable over Reutelingsperger (US 5,627,036) in view of Patz (EP 163 294) as applied to claims 66, 73-76 and 81-83 above, and further in view of Tait (US 5,632,986).

Reutelingsperger (as modified above) teaches that any form of annexin may be used for the radiopharmaceutical (see column 7, lines 29+), but fails to specifically recite that the annexin is annexin V.

Tait discloses that annexin V is a protein which binds to human platelets and may be used for *in vivo* targeting thereof, see column 3, lines 35+. Tait discloses that annexin V is a protein which binds to human platelets and may be used for *in vivo* targeting thereof, see column 3, lines 35+.

It would have been obvious to one of ordinary skill in the art to use annexin V as the targeting agent in the conjugates disclosed by Reutelingsperger because Reutelingsperger teaches that any annexin may be employed, and annexin V is known in the art as a protein that provides the specific advantage of targeting platelets *in vivo*, as shown by Tait.

Claims 79 and 80 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reutelingsperger (US 5,627,036) in view of Patz (EP 163 294) as applied to claims 66, 73-76 and 81-83 above, and further in view of Kruper Jr. (US 5,489,425).

Reutelingsperger (as modified above) teaches that annexins may be radiolabeled for use as radiodiagnostic agents by being conjugated to a chelating agent but fails to teach the conjugation through enzymatically cleavable linkers as claimed. However, the use of enzymatically cleavable linkers for

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conjugating a chelating agent to a targeting molecule is well known in the art to provide the advantage of organ clearance, as shown by Kruper Jr.

Kruper Jr. teaches the conjugation of a targeting agent to a chelating agent and teaches that enzymatically cleavable linkers (e.g., peptides, etc.) are preferred for such conjugation because they provide the advantage of being stable in the serum (e.g., to provide the desired targeting), while being cleavable in an organ to provide for clearance of the radioisotope, see column 4.

It would have been obvious to one of ordinary skill in the art to further modify Reutelingsperger, as modified by Patz, to include the use enzymatically cleavable linkers (e.g., peptides, etc.) because it is well known in the art that the use of such linkers in radiodiagnostic agents provides the advantage of being stable in the serum, while being cleavable in an organ (e.g., the liver) to provide for clearance of the radioisotope, thereby improving safety, as shown by Kruper Jr.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Omum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 66-83 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-21 of U.S. Patent 5,968,477. Although the conflicting claims are not identical, they are not patentably distinct from each other because the pending claims and patent claims are all drawn to conjugates comprising an annexin, a hexose moiety and NxSy chelators with only slight differences in describing the functionalities of the components. Claim 66 is generic to all that is recited in claim 1 of US Pat. 5,968,477. That is, claim 66 falls entirely within the scope of claim 1 of the patent, or is anticipated thereby. The only difference is that patented claim 1 requires a hexose

moiety in the conjugate, while instant claim 66, 72-76 and 79-83 are generic thereto. However, the hexose moiety is clearly encompassed by these claims, as such limitations are set forth in dependent claims, i.e., claims 67-71, 77 and 78.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(f) he did not himself invent the subject matter sought to be patented.

Claims 66-83 are rejected under 35 U.S.C. 102(f) because the applicant did not invent the claimed subject matter.

The claims are rejected over US 5,968,477. This patent shares at least one common inventor but has a both a different inventive entity and a different assignee with the '477 patent. The '477 patent has assignees of NeoRx Corp. and University of WA, while the instant application lists the assignee as NeoRx Corp.

The '477 discloses a conjugate as claimed, having an annexin, and NxSy chelator, as well as, a hexose moiety as claimed, see for example, the claims of the '477 patent. Since the claimed subject matter is fully disclosed by the '477 patent the claims are anticipated under 35 USC 102(f) thereby.

Conclusion

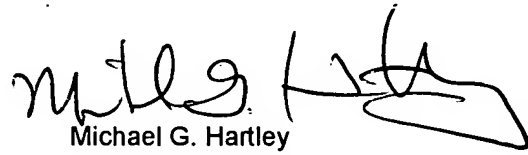
No claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael G. Hartley whose telephone number is (571) 272-0616. The examiner can normally be reached on M-Tu and Th-F, 7:30-4, Telework on Wed..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Michael G. Hartley
Primary Examiner
Art Unit 1618

7/5/2005